IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC.,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION and CENTER FOR VETERINARY MEDICINE,

Defendants.

JUDGE NATHAN

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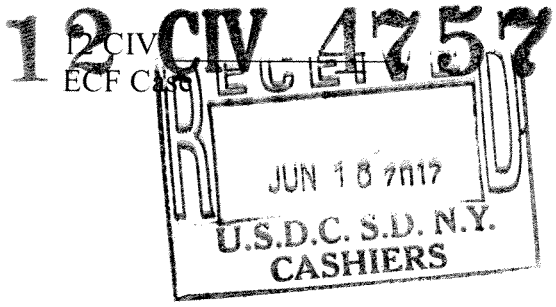
ECF CASE



COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiff Natural Resources Defense Council, Inc. (NRDC) asserts violations of the Freedom of Information Act (FOIA), 5 U.S.C. § 552, by defendants United States Food and Drug Administration (FDA) and Center for Veterinary Medicine (CVM) for failing to release responsive records requested by NRDC regarding defendants' risk assessments of antibiotics used in livestock production.

2. NRDC filed a FOIA request with FDA on April 20, 2012, seeking the results of any new qualitative microbial food safety risk assessments conducted by CVM for specific antibiotics used in livestock production, and all communications concerning any such risk assessments. FDA and CVM's response was due, at the latest, on June 8, 2012. Both agencies have failed to produce any documents in response to NRDC's FOIA request or to provide NRDC with a final response or determination as to whether the agencies will comply with the request.

3. NRDC requests a declaration that FDA and CVM have violated FOIA by failing to produce responsive records by the statutory deadline and by failing to provide a final response

or determination stating whether the agencies will comply with the request. NRDC also seeks an injunction ordering that FDA and CVM disclose by a certain date all non-exempt, responsive records to NRDC.

JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

5. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e)(1), because Plaintiff NRDC resides and has its principal place of business in this judicial district.

THE PARTIES

6. Plaintiff NRDC is a national, not-for-profit, environmental advocacy group with 357,000 members. It is headquartered in New York, New York. NRDC engages in research, public education, and litigation to improve the regulation of harmful substances in food, drugs, and consumer products.

7. Defendant FDA is a federal agency within the meaning of FOIA. *See* 5 U.S.C. § 551(1). FDA has possession or control of the records that NRDC seeks in this action.

8. Defendant CVM is a federal agency within the meaning of FOIA. *See id.* CVM has possession or control of the records that NRDC seeks in this action.

STATUTORY AND REGULATORY FRAMEWORK

9. FOIA mandates that an "agency, upon any request for records . . . shall make the records promptly available . . . ." *Id.* § 552(a)(3)(A).

10. Under FOIA, an agency must determine whether to comply with a FOIA request within twenty business days and "shall immediately notify the person making such request of such determination and the reasons therefor . . . ." *Id.* § 552(a)(6)(A)(i); *see* 21 C.F.R. § 20.41(b).

11. The twenty-day deadline for an agency to determine whether to comply with a FOIA request begins on the earlier of: (1) the date the request is first received by the "appropriate component of the agency" or (2) ten days after the request is first received by "any component of the agency that is designated in the agency's regulations . . . to receive [FOIA] requests . . . ." 5 U.S.C. § 552(a)(6)(A)(ii).

12. If an agency does not respond to a FOIA request by the statutory deadline, the requestor is deemed to have exhausted administrative remedies and may immediately pursue judicial review. *Id.* §§ 552(a)(6)(C)(i), 552(a)(4)(B).

THE FACTS

13. FDA has concluded that using the same antimicrobial drugs for production purposes in livestock as are used to treat infections in humans is not in the interest of protecting and promoting the public health. Research has shown that the use of antibiotics in livestock production leads to the development of antibiotic-resistant bacteria that can be transferred from animals to people through direct contact, environmental exposure, and the consumption and handling of contaminated meat and poultry products. People who contract antibiotic-resistant infections are more likely to have longer hospital stays, may be treated with less effective and more toxic drugs, and may be more likely to die as a result of the infection.

14. In 2003, FDA issued Guidance for Industry No. 152, which recommended an approach for drug sponsors to use "for assessing the safety of antimicrobial new animal drugs with regard to the microbiological effects on bacteria of human health concern." FDA, Guidance for Industry No. 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern* (2003). Although the Guidance applied by its terms to animal drugs that had not yet been approved by FDA, FDA has

acknowledged that the underlying concept is also applicable to safety evaluations conducted for previously approved antimicrobial animal drugs.

15. FDA has used the qualitative risk assessment approach set forth in Guidance for Industry No. 152 to evaluate the safety of at least some previously approved animal drugs.

16. By 2004, CVM had "completed microbiological food safety reviews of the last of seven approved penicillin and penicillin combination products," and "[r]eview of several approved tetracycline products [was] underway." CVM, *Annual Report, Fiscal Year 2004*, at 30.

17. In May 2004, the director of CVM sent letters to several drug sponsors reporting the results of new CVM risk assessments of previously approved animal drug products containing penicillin and/or tetracyclines.

18. In a December 2011 Federal Register Notice, FDA acknowledged that it had begun "to look at the safety of some . . . already approved drugs," based on its recognition that "already-approved antimicrobial new animal drugs also have antimicrobial resistance risks associated with their use." Withdrawal of Notices of Opportunity for a Hearing, 76 Fed. Reg. 79,697, 79,699 (Dec. 22, 2011).

19. On April 20, 2012, NRDC filed a FOIA request with FDA, via fax and overnight courier service to the address designated on FDA's website for receiving such requests. *See* 20 C.F.R. § 20.40(a).

20. NRDC's FOIA request seeks the results of any qualitative microbial food safety risk assessments of specific animal drug products that CVM has conducted since 2003, following the principles set forth in FDA's Guidance for Industry No. 152. The request also seeks communications concerning any such risk assessment(s), including internal agency

communications as well as communications with persons or entities outside of CVM or FDA, such as drug sponsors and/or their representatives. NRDC also sought a fee waiver.

21. According to the delivery records of the courier service, FDA received NRDC's request on April 23, 2012.

22. FDA's Division of Freedom of Information confirmed receipt of NRDC's FOIA request by letter dated April 26, 2012.

23. FDA granted NRDC's request for a fee waiver on May 7, 2012.

24. FDA and CVM's response was due, at the latest, on June 8, 2012. *See* 5 U.S.C. § 552(a)(6)(A)(i); 21 C.F.R. § 20.41(b).

25. To date, neither FDA nor CVM has produced any documents in response to NRDC's FOIA request.

26. To date, neither FDA nor CVM has provided NRDC with a final response or determination regarding whether FDA and CVM will comply with NRDC's FOIA request.

CLAIM FOR RELIEF

27. NRDC incorporates by reference all preceding paragraphs.

28. FDA and CVM have violated their statutory duty under FOIA, 5 U.S.C. § 552(a)(6), to release non-exempt, responsive records to NRDC.

29. NRDC has a statutory right under FOIA immediately to obtain all requested records that are not exempt from disclosure under FOIA.

REQUEST FOR RELIEF

WHEREFORE, plaintiff requests that this Court enter judgment against FDA and CVM as follows:

A. Declaring that defendants have violated FOIA by failing to produce non-exempt records responsive to plaintiff's FOIA request by the statutory deadline;

B. Ordering that defendants disclose all responsive, non-exempt records to plaintiff within fifteen days;

C. Awarding plaintiff its reasonable costs and attorneys' fees; and

D. Granting such other and further relief as the Court deems just and proper.

Dated: New York, New York
June 18, 2012

Respectfully submitted,

/Mitchell S. Bernard/

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